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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,951

04/20/2006

Brian Anderton

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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

11/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/562,951	Applicant(s) ANDERTON ET AL.	
	Examiner David J. Steadman	Art Unit 1656	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 November 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 10 November 2009. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☒ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☒ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 22,23,26,27,32,36,38,39,41,42 and 55.
 Claim(s) withdrawn from consideration: 31,33-35,40,43-46,53 and 54.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
 13. ☐ Other: _____.

/David J. Steadman/
Primary Examiner, Art Unit 1656

Continuation of 3. NOTE: The request for reconsideration in the reply filed on 11/10/09 has been fully considered. The amendment to the claims filed on 11/10/09 has not been entered because the claims as amended require further consideration as necessitating new rejections under 35 U.S.C. 112, first and second paragraphs. See MPEP § 714.13.

A new rejection under 35 U.S.C. 112, second paragraph, is required in view of the recitation of "greater at least 95% identity" in claim 22 because it is unclear as to the meaning of the noted phrase. Also, it is unclear as to what is referred to by the recitation of "said phosphorylation" in line 2 of part (b) of claim 22 - phosphorylation of tau in the preamble without recitation of particular amino acids, or phosphorylation in (a). Also, it is unclear from the recitation of "exposing...under conditions under which said casein kinase 1 or variant thereof phosphorylates said tau protein or variant thereof" as to whether or not the scope of CK1 variants is limited to those that phosphorylate tau at the recited tau positions since the conditions are inclusive of those under which SEQ ID NO:1 phosphorylates SEQ ID NO:2, i.e., a CK1 variant exposed to conditions under which SEQ ID NO:1 phosphorylates SEQ ID NO:2 is not indicative of tau phosphorylation by the CK1 variant. A new rejection under 35 U.S.C. 112, first paragraph, is necessitated by recitation of the range "greater at least 95% identity". Applicant's remarks in the amendment filed on 11/10/09 have been fully considered. However, in view of the non-entry of the amendment, applicant's arguments are not found persuasive to overcome the outstanding rejection(s) as set forth in the Office action mailed on 5/12/09 for the reasons of record stated therein. In the interest of compact prosecution, applicant's arguments are addressed below.

Continuation of 11. does NOT place the application in condition for allowance because: Addressing the rejection under 35 U.S.C. 112, second paragraph, applicant argues the rejection is obviated by claim amendment. This is not found persuasive at least because the claims remain indefinite with respect to whether or not the CK1 variant phosphorylates the tau or variant thereof. The recitation of "exposing...under conditions which said casein kinase 1 or variant thereof phosphorylates said tau protein or variant thereof" requires only that the exposing occurs under the recited conditions, and is not a positive recitation that the CK1 variant phosphorylates the tau or variant thereof. However, part (c) of claim 22 recites "the candidate substance which inhibits the phosphorylation", suggesting that phosphorylation occurs. Also, the claims remain unclear as to whether or not a tau variant is required to maintain the recited positions relative to tau of SEQ ID NO:2. If the scope of tau variants is not intended to maintain the amino acid numbering relative to SEQ ID NO:2, then, e.g., if the variant has a histidine tag placed at the N-terminus of SEQ ID NO:2, the recited numbering does not correspond to the tau variant amino acid numbering. Thus, even if the amendment filed on 11/10/09 were entered, the rejection under 35 U.S.C. 112, second paragraph would be maintained.

Addressing written description rejection under 35 U.S.C. 112, first paragraph, applicant argues the rejection is obviated by claim amendment in view of the specification's disclosure and the available prior art. Assuming the genus of CK1 variants of claim 22 is to be interpreted as not limited to those that phosphorylate tau and tau variants at the recited positions, the rejection would be withdrawn if the amendment were entered based on the guidance provided by Revision 1 of the Written Description Training Materials. Assuming the genus of CK1 variants of claim 22 is to be interpreted as being limited to those that phosphorylate tau and tau variants at the recited positions, the rejection would be maintained because, while an art-recognized correlation between the structure of CK1 of SEQ ID NO:1 and the function of phosphorylating tau of SEQ ID NO:2 at the recited positions may exist, the claims encompass CK1 variants that phosphorylate tau variants, where the variants are not required to maintain the same 3-D shape or conformation as SEQ ID NO:2. There is no disclosed or art-recognized correlation between the structure of a CK1 variant that has 95% identity to SEQ ID NO:1 and the function of phosphorylating a tau variant at the recited positions that has 95% identity to SEQ ID NO:2.

Addressing the scope of enablement rejection under 35 U.S.C. 112, first paragraph, applicant argues the rejection is obviated by claim amendment in view of the specification's disclosure and the state of the art. Assuming the scope of CK1 variants of claim 22 is to be interpreted as not limited to those that phosphorylate tau and tau variants at the recited positions, the rejection would be maintained because the method would encompass the use of inactive CK1 variants, which would not be useful for identifying phosphorylation inhibitors and the specification fails to provide guidance for using such methods. Assuming the scope of CK1 variants of claim 22 is to be interpreted as being limited to those that phosphorylate tau and tau variants at the recited positions, the rejection would be withdrawn.

Addressing the obviousness rejection under 35 U.S.C. 103(a), applicant argues the rejection is obviated by amendment and further argues the references fail to teach all limitations and there is no motivation to combine the cited references. This is not found persuasive at least because, as written, the claims require "exposing" only under conditions of phosphorylation of the recited residues and "said phosphorylation" can be interpreted to refer to the preamble's statement of "phosphorylation of a tau protein by casein kinase 1".

Addressing the double patenting rejection, applicant argues the rejection is obviated by amendment. This is not found persuasive at least because, as noted above, the claims require "exposing" only under conditions of phosphorylation of the recited residues and "said phosphorylation" can be interpreted to refer to the preamble's statement of "phosphorylation of a tau protein by casein kinase 1".